

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 77092 UvF/usj	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/DK 03/00167	International filing date (day/month/year) 14.03.2003	Priority date (day/month/year) 15.03.2002
International Patent Classification (IPC) or both national classification and IPC C12N1/16		
Applicant PHARMA NORD APS et al.		

- This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

- This report contains indications relating to the following items:
 - ☒ Basis of the opinion
 - ☐ Priority
 - ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Lack of unity of invention
 - ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Certain documents cited
 - ☐ Certain defects in the international application
 - ☐ Certain observations on the international application

Date of submission of the demand 02.10.2003	Date of completion of this report 29.06.2004
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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/DK 03/00167**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-18 as originally filed

Claims, Numbers

1-11 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 48.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:
- ☐ the description, pages:
 - ☐ the claims, Nos.:
 - ☐ the drawings, sheets:
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-11
	No: Claims	
Inventive step (IS)	Yes: Claims	1-11
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-11
	No: Claims	

2. Citations and explanations

see separate sheet

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1. It appears that with respect to the prior art, the subject-matter of present claims 1-11 may be considered novel and inventive according to Art. 33(2), (3) PCT.

In difference to the prior art methods described for producing a selenium yeast product for use in food etc., the present method involves the step of keeping the ethanol concentration during cultivation $\leq 1\%$. Document EP 0078500 generally refers to ethanol formation in yeast culture and describes attempts to regulate it. Document US 4,530,846 describes a process for producing an edible selenium yeast product but uses molasses as carbon source and does not mention controlling of ethanol concentration during culturing. Document WO 98/37172 equally refers to a method of producing a selenium-enriched yeast product and discloses inter alia an example wherein glucose is used as carbon source (example 5). However, ethanol concentration and its control are not mentioned and the results in selenium content are much lower than in the present case (yeast mass containing 684 ppm compared to 1,380 ppm or 1,355 ppm as described in present example 1).

Document Newsletters of Sabinsa Corporation, 1999, mentions that "... estimates of protein-bound L-selenomethionine in different manufactured lots suggest a range of 20-50% of yeast Se in protein is bound L-selenomethionine. Both, document WO 98/37172 and US 4,530,846 are silent with respect to the content of bound L-selenomethionine. The present application refers to a selenium yeast product wherein inter alia the content of L-selenomethionine constantly constitutes at least 55%.

It therefore further appears that the subject-matter of claims 1-11 may be considered novel and inventive in the sense of Art. 33(2), (3) PCT.

2. In case the application enters the regional phase, the applicant is pointed to some unclarities. It appears that the claimed selenium yeast product is the result of the process as set out in claims 1-6, see also claim 8), though this is not expressis verbis mentioned in the description or demonstrated in the examples or part of claims 1-6. Part c) of claim 7 referring to a much more general method of obtaining the claimed product is thus not considered to be sufficiently supported by the description which again may give raise to doubt whether the process of claims 1-6 and the product of claim 7 are linked by a common inventive special technical feature.

The application emphasis that nutrients and selenium are added to the culture (continuously) at a rate corresponding to the consumption rate of the substances in the yeast (see e.g. page 6, lines 21-23 and page 11, lines 16-17). This is

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however not clearly reflected in claim 1 (see step i) and step v)).